Appendix A

Claim Amendments

1. (Currently amended) A pharmaceutical formulation comprising a pharmaceutical acceptable salt of glycopyrronium, a solvate ~~solvates~~ or physiologically functional derivative thereof in combination with an active pharmaceutical ingredient being a compound selected from the group consisting of roflumilast, pharmaceutically acceptable salts of roflumilast, solvates of roflumilast **[[or]]** and physiologically functional ~~derivative~~ derivatives thereof; and a pharmaceutically acceptable carrier and/or one or more excipients~~, and optionally one or more other therapeutic ingredients~~.

2. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and roflumilast are contained in the same pharmaceutical formulation (fixed combination).

3. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and roflumilast are contained in different pharmaceutical formulations (free combination).

4. (Currently amended) ~~Formulation~~ The formulation according to claim 1, comprising a compound selected from the group consisting of N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide, 3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloropyrid-4-yl 1-oxide)benzamide, **[[**and**]]** salts thereof **[[**or**]]** and solvates thereof.

5. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is selected from **[[**form**]]** the group consisting of ~~compounds~~ racemic forms [S,S-, S,R-, R,S- and R,R-forms] of the pharmaceutical acceptable salt of glycopyrronium in any mixing ratio and enantiomerically enriched S,S-, S,R-, R,S- and R,R-forms of the pharmaceutical acceptable salt of glycopyrronium.

6. (Currently amended) ~~Formulation~~ The formulation according to claim 5, wherein the enantiomerically enriched form of the pharmaceutical acceptable salt of glycopyrronium is the R,R-form (i.e. (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium).

7. (Currently amended) ~~Formulation~~ The formulation according to claim 6, wherein the R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess ~~(ee), preferably 95 % ee, more preferably more than 98 % ee, and in particular preferably more than 99.5 % ee~~.

8. (Currently amended) ~~Formulation~~ The formulation according to claim 1 wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R- and/or R,S- forms.

9. (Currently amended) ~~Formulation~~ The formulation according to claim 1, comprising pharmaceutical acceptable salt of glycopyrronium and roflumilast in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal, ~~such as a human,~~ for which a PDE 4 inhibitor and/or an anticholinergic agent is indicated.

10. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for administration by inhalation.

11. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for nasal administration.

12. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein roflumilast is present in a form for oral administration and the [[a]] pharmaceutical acceptable salt of glycopyrronium is present in a form suitable for administration by inhalation.

13. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 1, which is a dry powder and the carrier is a saccharide.

14. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 13, wherein the carrier is lactose monohydrate.

15. (Currently amended) ~~Method for the prophylaxis or~~ A method of treatment of a clinical condition in a mammal, ~~such as a human,~~ for which a PDE 4 inhibitor and/or an anticholinergic agent is indicated, which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising roflumilast or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with a pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

16. (Currently amended) ~~Method~~ The method according to claim 15, wherein the clinical condition is selected from the group consisting of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic bronchitis, [[and]] wheezy bronchitis, emphysema, respiratory tract infection, [[and]] upper respiratory tract disease, rhinitis, allergic rhinitis and seasonal rhinitis.

17. (Currently amended) ~~Method~~ The method according to claim 16, which comprises a twice daily dosage regimen.

18. (Currently amended) ~~Method~~ The method according to claim 16, which comprises a once daily dosage regimen.

19. (Currently amended) ~~Method~~ The method according to claim 16, which comprises administration of a combination of [[the]] a pharmaceutical acceptable salt of glycopyrronium and roflumilast in the same administration form by inhalation from an inhaler and wherein each actuation provides a dose therapeutically

effective for a twice daily dosing regiment or for a once daily dosing regiment.

20. (Currently amended) ~~Dry~~ A dry powder inhalation product comprising a pharmaceutical composition according to claim 13.